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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,882

08/17/2005

Michael Lyne

GJE-7477

1606

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08/10/2006

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/517,882	LYNE, MICHAEL	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/18/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The preliminary amendment filed on December 13, 2004 have been received and entered into the application. Accordingly, claim 1 has been cancelled and claim 4 has been added. Currently, claims 2-4 are pending and being examined.

Specification

The disclosure is objected to because of the following informalities: The period is missing at the end of the specification page 3.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Fasmer et al. (1987) of record.

Fasmer et al. teach the antinociceptive effects of (+)-nefopam in mice. (abstract). Fasmer et al. teach that the antinociceptive activity of (+)-nefopam was significantly more potent than (-)-nefopam. (abstract). **Fasmer et al. teach that (+)-nefopam was dissolved in 0.9% NaCl.** (page 508, under materials and methods). Fasmer's

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teaching of 0.9% **NaCl** to dissolve (+)-nefopam anticipates the claimed limitation of the "solubility enhancer" set forth in claim 3 because NaCl combined with (+)-nefopam promotes the dissolution of (+)-nefopam. Further, Applicants' recitation in claim 2 of a composition suitable for intranasal administration does not represent a patentable limitation because such fails to impart any physical limitation to the same composition taught by the cited prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fasmer et al. (1987) of record in view of Keller et al. (U.S. Patent No. 6,585,958 B1).

Fasmer et al. teach the antinociceptive effects of (+)-nefopam in mice. (abstract). Fasmer et al. teach that the antinociceptive activity of (+)-nefopam was significantly more potent than (-)-nefopam. (abstract). Fasmer et al. teach that (+)-nefopam was dissolved in 0.9% NaCl. (page 508, under materials and methods). Fasmer et al. teach that nefopam is an effective analgesic in man and its **analgesic activity** can also be demonstrated in some of **tests of nociception** in animals. (page 508, left-hand

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column). Fasmer et al. teach in conclusion, that (+)-nefopam is more potent as an **analgesic** than the (-) enantiomer. (page 511, right-hand, column, 3rd full paragraph).

Fasmer et al. do not teach the intranasal administration for treatment of pain set forth in claim 4.

Keller et al. teach a composition comprising **analgesics** such as **nefopam** that can be prepared and used for a medicinal aerosol in particular for a **nasal** aerosol. (column 8, lines 3-8, 18, 48-50; column 11, lines 30-31). Keller et al. teach that their nefopam composition can optionally be used in the form of **isomers, enantiomers or racemates**. (column 9, lines 24-26). Keller et al. teach that an aerosol formulation offer a number of advantages having improved suspension and shelf-life properties of formulation and improvement in the dosage accuracy. (column 11, lines 20-25).

It would have been obvious to one of ordinary skill in the art to modify the injectable administration of (+) nefopam taught by Fasmer et al. for intranasal administration for treatment of pain because Keller et al. teach that any form of nefopam including isomers, enantiomers or racemates can be formulated for a nasal aerosol composition and that a nasal aerosol composition offers a number of advantages such as improved suspension and shelf-life. Further, the nasal aerosol formulation of nefopam provides improved dosage accuracy. One of ordinary skill in the art would have been motivated in particular to administer (+) nefopam intranasally for the treatment of pain in order to achieve an expected benefit of superior analgesic activity of (+)-nefopam taught as by Fasmer et al. and to advantageously deliver an accurate dosage to the patient suffering from severe pain as taught by Keller et al.

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For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in dark ink, appearing to read 'Jennifer Kim', is written over a horizontal line.

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
August 7, 2006